JUN 2 6 2000

Attachment 4

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
Cholinesterase Assay for Bayer ADVIA® Integrated Modular System (IMS™)

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Device Act of 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K001344

1. Intended Use

This *in vitro* method is intended to quantitatively measure cholinesterase (CHE) in human serum and plasma (lithium heparin) using ADVIA IMS CHE Assay on a *Bayer ADVIA®* Integrated Modular System. Measurements of CHE are used in the detection of organophosphorus poisoning and certain liver diseases.

2. Predicate Device

Product Name	Reagent Part #	Calibrator Part #
CHEM 1 Cholinesterase Assay	T01-3203-53	T95-1047

3. Device / Method

Product Name	BAN	Calibrator Part #
ADVIA IMS CHE Assay	01681077	B21-4340-01

Imprecision

ADVIA IMS	
Level (KU/L)	Total CV(%)
3.9	2.2
6.2	1.8
8.0	1.7

CHEM 1	
Level (KU/L)	Total CV(%)
3.7	2.4
5.3	2.1
6.5	2.0

Correlation (Y= ADVIA IMS, X=comparison system)

Specimen type	Comparison System (X)	N	Regression Equation	Syx (KU/L)	R	Sample Range (KU/L)
Serum	CHEM 1	75	Y=0.96X – 0.21	0.10	0.999	0.4 - 11.0
Plasma(y), Serum(x)	ADVIA IMS	58	Y=0.96X – 0.17	0.16	0.997	4.8 – 12.4

Date

Regulatory Affairs
Bayer Corporation
511 Benedict Avenue
Tarrytown, New York 10591-5097

Interfering Substances (Serum)

Interfering Substance	Interfering Substance Concentration (mg/dL)	CHE Concentration (KU/L)	Effect (% change)
Hemoglobin	500	3.7	1
Bilirubin (Unconjugated)	25	3.7	2
Bilirubin (Conjugated)	20	3.8	-1
Lipids (Triglycerides)	500	3.7	3
Total Protein	10,100	4.3	3

Analytical Range

~~0~~ – 24.0 KU/L

0.3

Date

Regulatory Affairs
Bayer Corporation
511 Benedict Avenue
Tarrytown, New York 10591-5097

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
Phenytoin Method for ADVIA® IMS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Device Act of 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K001344 (leave blank)

1. Intended Use

The Bayer *ADVIA IMS* Phenytoin method is an *in vitro* diagnostic device intended to measure phenytoin, an antiepileptic drug, in human serum. Measurements of phenytoin are used as an aid in the diagnosis and treatment of phenytoin overdose and in monitoring therapeutic levels of phenytoin to ensure appropriate therapy.

2. Predicate Device

Product Name	Reagent Part #	Calibrator Part #
Bayer RA-1000 Phenytoin	T01-1879-01	T03-2953-01

3. Device / Method

Product Name	Reagent BAN	Calibrator BAN	Phenytoin Sample Diluent BAN
ADVIA IMS Phenytoin	100 Tests 06257397 250 Tests 03176841	Phenobarbital/ Phenytoin 08678004	02259891

Minimum Detectable Concentration

Method	ADVIA IMS	RA-1000
MDC	0.11 µg/mL	0.5 µg/mL

A. Imprecision

ADVIA IMS	
Level µg/mL	Total CV (%)
5.1	3.3
10.0	2.2
20.0	2.2

Bayer RA-1000	
Level µg/mL	Total CV(%)
3.8	2.9
12.0	1.7
21.5	1.5

B. Correlation (Y=ADVIA IMS, X=Comparison system)

Specimen type	Comparison System (X)	N	Regression Equation	Syx µg/mL	R	Sample Range µg/mL
Serum	RA-1000	46	Y= 0.94X - 0.02	0.74	0.997	5.0 to 35.6

C. Interfering Substances

Interfering Substance	Interfering Sub. Conc. (mg/dL)	Phenytoin Concentration µg/mL	Effect (% change)
Bilirubin (unconjugated)	25	10.0	-2
Bilirubin (conjugated)	20	10.7	-1
Hemoglobin	600	10.3	+2
Lipids (Triglycerides)	1000	10.4	+2

Analytical Range 0.11 to 40.0 µg/mL

Date _____

Bayer Corporation, Business Group Diagnostics
Tarrytown, NY.

Regulatory Affairs

914-524-3494 (fax 914-524-2500)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 2 6 2000

Mr. Fredrick Clerie
Director Regulatory Affairs
Bayer Corporation
Business Group Diagnostics
511 Benedict Avenue
Tarrytown, New York 10591-5097

Re: K001344
Trade Name: ADVIA IMS Cholinesterase Assay
ADVIA IMS Phenytoin Assay
Regulatory Class: I
Product Code: DIH
Regulatory Class: II
Product Code: DKH
Dated: April 24, 2000
Received: April 27, 2000

Dear Mr. Clerie:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K001344

Device Name: **ADVIA IMS Cholinesterase Assay**

Indications For Use:

The Bayer Advia IMS Cholinesterase method is an *in vitro* diagnostic device intended to measure CHE activity in human serum or plasma. Such measurements are used as an aid in the diagnosis and treatment of organophosphorus poisoning and certain liver diseases such as cirrhosis, acute and chronic hepatitis.

Device Name: **ADVIA IMS Phenytoin Assay**

Indications For Use:

The Bayer Advia IMS Phenytoin method is an *in vitro* diagnostic device intended to measure phenytoin, an antiepileptic drug, in human serum. Measurements of phenytoin are used as an aid in the diagnosis and treatment of phenytoin overdose and in monitoring therapeutic levels of phenytoin to ensure appropriate therapy.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number 6/23/00

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ___
(Per 21 CFR 801.109)

Optional Formal 1-2-96